

ORIGINAL

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Attorneys for Plaintiff
UNITED STATES OF AMERICA

FILED IN THE
UNITED STATES DISTRICT COURT
DISTRICT OF HAWAII

MAY 13 2015

at 11 o'clock and 25 min. A.M.
SUE BEITIA, CLERK

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

UNITED STATES OF AMERICA,) CR. NO. **CR 15-00322 SOM**
)
Plaintiff,) INFORMATION
)
vs.) Introduction of an
XANYA SOFRA-WEISS,) Adulterated Device into
) Interstate Commerce, in
Defendant.) Violation of 21 U.S.C. §§
) 331(a), 351(f)(1)(B), and
) 333(a)(1)
)

INFORMATION

The United States Attorney charges:

From on or about October 20, 2010, to and including on or about December 31, 2010, within the District of Hawaii and elsewhere, the defendant XANYA SOFRA-WEISS, did introduce, deliver for introduction, and cause the introduction and delivery for introduction into interstate commerce, a "device" as defined in Title 21, United States Code, Section 321(h), that was adulterated, to wit, an "Ion Magnum III", a device sold by Defendant that: did not have pre-market approval from the Food and Drug Administration (FDA) as required by Title 21, United States Code, Section 360e; had no FDA-granted investigational device exemption pursuant to Title 21, United States Code, Section 360j(g); for which Defendant did not submit a pre-market notification to the FDA, pursuant to Title 21, United States Code, Section 360(k); and for which Defendant did not obtain an FDA finding of substantial equivalence, pursuant to Title 21, United States Code, Section(s) 360c(f)(1) and 360c(i), which was sold by Defendant to A.K., and shipped in interstate commerce from Hawaii to California.

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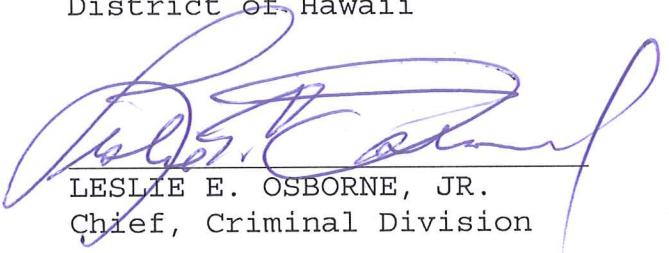
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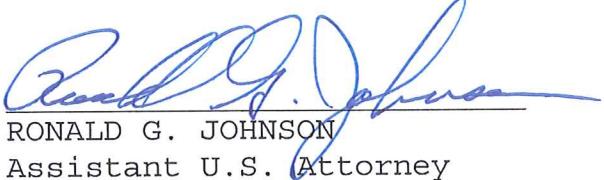
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All in violation of Title 21, United States Code, Sections 331(a), 351(f)(1)(B), and 333(a)(1).

DATED: May 13, 2015, Honolulu, Hawaii.

FLORENCE T. NAKAKUNI
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UNITED STATES vs. XANYA SOFRA-WEISS
Cr. No.
"Information"